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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,371	03/22/2001	Graham McCreath	8117-14	4297

23973 7590 06/18/2003

DRINKER BIDDLE & REATH  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA, PA 19103-6996

EXAMINER

WEBER, JON P

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/814,371	<b>Applicant(s)</b> MCCREATH ET AL.	
	<b>Examiner</b> Jon P Weber, Ph.D.	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5,9,12-15,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 9, 12-15 and 30-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

*Status of the Claims*

The response with amendments filed 11 April 2003 has been received and entered. Claims 1-3, 5, 9, 12-15 and 30-31 have now been presented for examination.

*Claim Rejections - 35 USC § 103*

Claims 1-3, 5, 9, 12-15 and 30-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Garner et al. (US 5,639,940) in view of Tripodi (WO 9213495) and further in view of Vukovich et al. (1980) and Lord (US 6,037,457).

It is argued that Garner et al. (US 5,639,940) do not disclose a specific combination of purification methods and that the secondary references do not remedy this deficiency. In particular it is asserted that the PEG precipitation suggested by Tripodi is contrary to the instant invention because PEG precipitates casein with the fibrinogen and the  $\epsilon$ -aminocaproic acid is only a buffer component of which PEG is the main ingredient. It is urged that Tripodi uses multiple precipitation steps. It is urged that neither Vukovich et al. nor Lord teach the two-step purification method instantly claimed.

It is agreed that at page 4, lines 10-27 of the instant disclosure it is asserted that PEG precipitates casein with the fibrinogen. However, at page 13, lines 18-24 of the instant disclosure, PEG is suggested to be a perfectly suitable precipitant of fibrinogen from among several precipitants disclosed. This second disclosure indicates that PEG can be used by adjusting the concentration. Hence, there is no basis for asserting that the use of PEG by Tripodi is contrary to the instantly claimed invention. The arguments are not consistent with the instant disclosure.

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The instant claims only require in step (a), that the desired protein be precipitated. There is no limit to the number of successive precipitations performed. Further, at page 14, lines 6-8 of the instant disclosure, states that the precipitation step can be advantageously performed up to approximately four times.

It has been previously identified that the  $\epsilon$ -aminocaproic acid-containing buffer in Tripodi prevents premature conversion of the fibrinogen by the plasmin. In Tripodi, the fibrinogen is being separated from plasma, which has a higher concentration of plasmin than milk, and therefore inhibiting the plasmin action is a more severe consideration.

Garner et al. and Lord both indicate that purifying fibrinogen by precipitation and chromatography is conventional in the art; therefore, using these two steps is reasonably suggested. Both Vukovich et al. and Lord were cited primarily for teaching that HIC was a well-known method of further purifying fibrinogen. Lord also provided further motivation to combine the references.

Applicant's arguments filed 11 April 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103 is adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

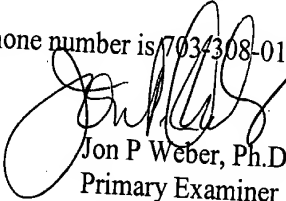
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
June 16, 2003